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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,955	10/18/2005	Qing Zhu	0149-P03068US00	1020

110 7590 03/27/2007

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EXAMINER	
SNYDER, STUART	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,955	ZHU ET AL.	
	Examiner	Art Unit	
	Stuart W. Snyder	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *7-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-6, drawn to a cell-line that replicates HCV, in the reply filed on 1/22/2007 is acknowledged. The traversal is on the ground(s) that: 1) The examiner of the corresponding PCT case did not find Lack of Unity and therefore Lack of Unity finding in the instant case is improper and 2) the claims are amended and are not anticipated by examiner-cited art. This is not found persuasive because:

   1) The MPEP explicitly states that an examiner may require election of a single invention during the national stage application **without qualification regarding PCT Chapter I stage decisions** (see MPEP 1893.03(d)[R-3]); and

   2) even with the explicit exclusion of monkey, chimpanzee, mosquito and human non-hepatic origin of the cell-lines, the amended claims still do not encompass a special technical feature; claims 1-3 are rejected below under 35 USC 102(b) because of a specific teaching by the prior art regarding the infectability of porcine and human non-hepatic cell lines (see items 3 and 4 below).

Applicant further requested rejoinder of Groups I and III. Applicant is reminded that rejoinder of product and process of making will be considered if the product claims are found allowable.

The requirement is still deemed proper and is therefore made **FINAL**. Claims 1-6 are therefore subject to examination and 7-19 are withdrawn from examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The original claims did not recite the current negative limitations of several claims, including claims 1 and 4, "non-chimpanzee, non-mosquito". Applicant does not state the specific section of the original specification wherein support can be found for amendments to claims 1 and 4. However, applicant did cite p 27, lines 13-14 as support for similar amendments to claim 11; the apparent support for the amendments is extremely broad—e.g., "any cell which supports production of HCV components". The specific exclusion of chimpanzee and mosquitoes of claims 1 and 4 is not implicit in the specification, on page 27 or elsewhere. Indeed, the specification and claims are so broad as to arguably overlap with the issued US patent (US 5,968,775 and see 102 rejection below) cited in the ISR for PCT/US03/39722.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton, *et al.* Claim 1 is drawn to a cell-line selected from a group consisting of "...a human, non-hepatic cell line"; claims 2-3 further limit the source of human cell lines to epithelial and HeLa cell lines, respectively. Houghton, *et al.* teaches generation and use of human cell lines including B- and T-cell lines (see claim 1; specification column 2, lines 44-54; specification column 11, line 36 and following section). Houghton, *et al.* specifically names HeLa cells in column 14, line 6 of the specification when listing candidate cell lines naturally producing suspected HCV receptors and coreceptors. Thus, all of the limitations of claims 1-3 are taught by Houghton, *et al.* and are properly rejected under 35 USC 102(b) as being anticipated by Houghton, et al.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Seipp, *et al.* Claim 1 is drawn to a cell-line selected from a group consisting of "...non-monkey cell line, a non-chimpanzee cell line, a non-mosquito cell line...". Seipp, *et al.* teaches use of human and non-human cell lines including porcine non-hepatoma cell lines supporting HCV replication. Seipp, *et al.* specifically names STE cells in Figure 4 as a cell line supporting HCV replication as evidenced by using culture

supernatant to infect uninfected cells and measuring HCV in the supernatant of infected cell cultures up to 130 days post-infection. Thus, all of the limitations of claim 1 are taught by Seipp, *et al.* and are properly rejected under 35 USC 102(b) as being anticipated by Seipp, et al.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kato, et al. Claim 1 is drawn to a cell-line selected from a group consisting of "...non-monkey cell line, a non-chimpanzee cell line, a non-mosquito cell line...". Kato, *et al.* teaches use of a human non-neoplastic cell line of hepatic origin supporting HCV replication. Kato, *et al.* specifically names PH5CH cells as a cell line supporting HCV replication as evidenced by measuring HCV in the supernatant of infected cell cultures up to 30 days post-infection and the increasing approach to homogeneity of a hypervariable region of the HCV genome, to wit, HVR1. Thus, all of the limitations of claim 1 are taught by Kato, *et al.* and are properly rejected under 35 USC 102(b) as being anticipated by Seipp, et al.

6. Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Sasagawa, et al. Claims 1, 4, and 5 are drawn to a cell-line selected from a group consisting of "...non-monkey cell line, a non-chimpanzee cell line, a non-mosquito cell line..." (claim 1), of mouse hepatic origin (claim 4) and are Hepa1-6 cells. Sasagawa, *et al.* teaches use of Hepa1-6 cells but does not teach an HCV replicative capacity. However, the present application teaches replication of HCV in Hepa1-6 cells and so the capacity to replicate HCV is an inherent property of Hepa1-6 cells Thus, all of the limitations of claims 1, 4, and 5 are taught by

Sasagawa, *et al.* and are properly rejected under 35 USC 102(b) as being anticipated by Sasagawa, et al.

7. Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu, et al. Claims 1, 4, and 5 are drawn to a cell-line selected from a group consisting of "...non-monkey cell line, a non-chimpanzee cell line, a non-mosquito cell line..." (claim 1), of mouse hepatic origin (claim 4) and are AML12 cells. Wu, *et al.* teaches use of AML12 cells but does not teach an HCV replicative capacity. However, the present application teaches replication of HCV in AML12 cells and so the capacity to replicate HCV is an inherent property of AML12 cells Thus, all of the limitations of claims 1, 4, and 5 are taught by Wu, *et al.* and are properly rejected under 35 USC 102(b) as being anticipated by Wu, et al.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder
Examiner
Art Unit 1648

SWS

Bruce Campell

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